HOUSE OF REPRESENTATIVES
THIRTY-THIRD LEGISLATURE, 2026
STATE OF HAWAII

H.B. NO. 2164

A BILL FOR AN ACT

RELATING TO WORKERS' COMPENSATION.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that workers' compensation costs and transparency are critical to maintaining fair and predictable benefits for injured workers while controlling employer expenses. The legislature further finds that compounded prescription drugs can provide essential therapeutic options for injured workers when commercially available FDA approved medications are unsuitable due to allergies, dosage requirements, or other clinical needs. However, inconsistent definitions have led to confusion. Federal law under section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) establishes clear standards for pharmacy compounding, including patient specific prescriptions, quality requirements for bulk substances, and exclusions for simple reconstitution. Aligning state law with these standards will promote patient safety by ensuring compounded drugs meet recognized quality benchmarks, enhance regulatory consistency between state and federal oversight.

Accordingly, the purpose of this Act is to align state law with federal standards for pharmacy compounding by codifying the federal definition of a "compounded drug", thereby promoting regulatory consistency, supporting patient safety, and ensuring access to individualized medications when an FDA approved drug is not medically appropriate for a particular patient. This Act incorporates by reference section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) and clarifying federal guidance.

SECTION 2. Section 386-21.7, Hawaii Revised Statutes, is amended by amending subsection (f) to read as follows:

"(f) For purposes of this section[~~, "equivalent~~]:

"Compounded prescription drug" means a drug product that is compounded by a licensed pharmacist in a state licensed pharmacy, or a licensed physician, for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, and otherwise meets the requirements of title 21 United States Code section 353.

"Equivalent generic drug product" has the same meaning as provided in section 328-91."

SECTION 3. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 4. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 5. This Act shall take effect on July 1, 2026.

INTRODUCED BY: _____

JAN 26 2026

H.B. NO. 2164

Report Title:
Workers' Compensation; Benefits; Compounded Prescription Drugs

Description:
Defines compounded prescription drugs for the purposes of workers' compensation law.

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